

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for calcium absorbability in mice, does not reasonably provide enablement for calcium absorbability in humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.
3. Level of skill in the art: Absorbability of calcium in mice does not need to hold true in humans. What holds true for one species does not need to hold true for other ones.
4. The presence of Examples: The example provided by the applicant has a limited showing with respect to calcium absorbability in mice (no other animals).
5. Level of Unpredictability: A limited showing with respect to mice does not translate to all animals including humans. There is no way to predict how other species will behave. Even if it shows some effect in mice, it is unclear how the casein phosphopeptides (CPP) will affect absorbability of calcium in humans. Just because casein phosphopeptides affect calcium absorbability in mice, it does not necessarily translate to humans.

6. For these reasons, the applicant is not entitled to a patent of this broad a scope.
7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 5, 7-8, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Use of trademarks such as "Alcalase" etc. makes the claims indefinite.

Allowable Subject Matter

10. Claims 1-4, 6 and 9-11 are allowed. Claims 5, 7, 8 and 12-20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action. The prior art fails to teach the proteolysis of heated whole or skim milk.

The following reference is the state of the art:

Jolly (US 4,107,334).

11. Jolly discloses the preparation of functional protein by heat denaturing whey, microbial or vegetable proteins and subjecting the denatured protein to enzymatic proteolysis using a designated minimum amount of enzyme (Abstract).
12. Jolly teaches the use of neutral, acidic or alkaline proteases for the enzymatic hydrolysis of isolated proteins. (Col. 4, lines 17-30)

Art Unit: 4174

13. Jolly explains the enzymatic hydrolysis conditions and the optimal temperature and pH. (Col. 4, lines 51-62).
14. Jolly discusses the enzyme deactivation at the end of the enzymatic hydrolysis of the isolated proteins. (Col. 4, lines 63-68)
15. Jolly discloses that the functional proteins prepared by his method are useful in a broad range of food compositions, they are soluble in a wide pH range, they are heat stable, have low viscosity in solution and excellent dispersability, aerating, emulsifying and texturizing properties. (Col. 5, lines 17-23)
16. Jolly does not teach the proteolysis of heated whole or skim milk.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hamid R. Badr whose telephone number is 5172703455. The examiner can normally be reached on M-F 7:30-5:00 ET (First Friday Off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on 5712721515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4174

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